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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,542	07/01/2003	David A. Ferrera	MICRU:64958	4965
24201	7590	08/04/2005	EXAMINER	
FULWIDER PATTON LEE & UTECHT, LLP			MARMOR II, CHARLES ALAN	
HOWARD HUGHES CENTER			ART UNIT	PAPER NUMBER
6060 CENTER DRIVE			3736	
TENTH FLOOR				
LOS ANGELES, CA 90045			DATE MAILED: 08/04/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/611,542	FERRERA, DAVID A.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 May 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 15-21 and 23-26 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 15-21 and 23-26 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 01 July 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed May 9, 2005. The examiner acknowledges the cancellation of claims 1, 22, 27 and 28. Claim 15-21 and 23-26 are pending.

Terminal Disclaimer

2. The terminal disclaimer filed on March 14, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,165,140, U.S. Patent No. 6,432,066 and U.S. Patent No. 6,595,932 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 15-21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viera ('699) in view of Frechette et al. ('155). Viera teaches a composite guidewire including an elongate, flexible NiTi core, a reinforcement tube disposed over a proximal region of the core, and a primary coil. The reinforcement tube appears to include a tapered distal region, and since no special definition is set forth for the term "distal region," it can be said that the distal tapered region of the reinforcement tube extends over a portion of the distal region of the core. The tube

is formed of a material having a greater stiffness than the core which may include stainless steel hypotube or a nickel titanium alloy having a greater stiffness than the core. The coil may be a platinum wire. The distal tip includes a bead formed on the end of the platinum coil. Viera teaches all of the limitations of the claims except for the coating of heat shrinkable material. Frechette et al. teach a composite guidewire with a coating of heat shrinkable material (PTFE). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a coating of heat shrinkable material similar to that of Frechette et al. to cover the reinforcement tube and proximal end of the coil a guidewire similar to that of Viera in order to aid in the insertion of the guidewire into the body, as well as to aid in securing the coil and reinforcement tube to the core so these elements do not separate from the core (see Frechette et al. column 1, lines 15-19). It would have been an obvious engineering design choice to make the core of the guidewire a hypotube as such hypotubes are well known in the art for such purposes.

Response to Arguments

5. Applicant's arguments filed May 9, 2005 have been fully considered but they are not persuasive. Applicant contends that Figure 3 of Viera shows the sleeve 340 extending over the proximal segment 322 of the corewire 320; that Frechette et al. does not teach a coating of a heat shrinkable material disposed over a distal tapered portion of a reinforcement tube; and that neither reference cited teaches a problem of possible flaring of the end of a reinforcement tube over a distal region of a guidewire core, or the solution of disposition of a coating of a heat

shrinkable material over a thinly tapered portion of a reinforcement tube over a distal region of a guidewire core. These arguments are not persuasive.

With respect to Viera, as noted in the rejection set forth hereinabove, no special definition is set forth for the term “distal region” in the specification of the instant application. While the Examiner does not dispute that Figure 3 of the Viera patent shows the sleeve 340 extending over the proximal segment 322 of the core wire 320, there is nothing in the Viera patent that states that the sleeve is limited to only the proximal segment of the core wire. Viera states at column 2, lines 44-46 that the “elongated sleeve 340 surrounding *at least a portion* of the core wire 320, *as illustrated in FIG. 3.*” This sentence clearly implies that the reinforcement tube may extend further than the proximal segment of the core. This position is supported by the sentence spanning lines 46-51 of column 2 of the Viera patent which suggest that the reinforcement tube may have any length depending on the size of the blood vessel and the location of the target region within the patent. Column 4, lines 4-55 of the Viera patent provide further disclosure of the reinforcement tube, and appear to require only that the tube provide a proximal portion of the guidewire with a stiffness that facilitates pushing of the guidewire and a “relatively flexible portion *toward distal end 302*” to facilitate at least the steering of the guidewire. Therefore, absent any special definition set forth in the instant application for the limitation “distal region,” it can be said that the distal tapered region of the reinforcement tube of Viera extends over a proximal portion of the distal region of the core.

The Frechette et al. patent clearly teaches the use of a heat shrinkable material to ensure that a coiled section does not separate from the core wire, if for instance the coil breaks (see column 1, lines 15-19). The Frechette et al. patent also teaches that the heat shrinkable sleeve 54

extends over a substantial portion of the core wire, including a tapered distal region thereof (see Figure 1). The Examiner respectfully submits that the heat shrinkable sleeve 54 of Frechette et al. could be disposed over a portion of the core wire that bears a distal portion of the reinforcement tube and will secure, not only the coil to the core wire to prevent relative separation therebetween, but will be equally effective in securing any other structural element disposed beneath the heat shrinkable sleeve 54 to the core wire as well, such as sleeve 50.

With respect to Applicant's argument that neither reference cited teaches a problem of possible flaring of the end of a reinforcement tube over a distal region of a guidewire core, or the solution of disposition of a coating of a heat shrinkable material over a thinly tapered portion of a reinforcement tube over a distal region of a guidewire core. Frechette et al. teach a similar problem, i.e. preventing a secondary structural element (coil) from separating from the core wire. Frechette et al. teaches a similar solution to the problem, i.e. disposing a heat shrinkable material over the secondary structural element (coil) to securely connect the secondary structural element to the core wire. It would have been apparent to one having ordinary skill in the art that the heat shrinkable material of Frechette et al. would be equally effective in securing any secondary structural element to the core wire, whether the secondary structural element be the coil or a reinforcement tube similar to that of Viera.

In view of the foregoing, the rejection of claims 15-21 and 23-26 under 35 U.S.C. 103(a) as being unpatentable over Viera ('699) in view of Frechette et al. ('155) has been maintained.

6. Applicant's arguments, see pages 7-8 of the Remarks, filed March 14, 2005, with respect to obviousness type double patenting rejections in view of U.S. Patent No. 6,156,140; U.S. Patent No. 6,432,066; and U.S. Patent No. 6,595,932 have been fully considered and are persuasive. The obviousness type double patenting rejections with respect to claims 15-21 and 23-26 have been withdrawn.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

cam
July 28, 2005